



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2013-N-0002]

Oral Dosage Form New Animal Drugs; Clindamycin; Enrofloxacin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during April 2013. FDA is also informing the public of the availability of summaries for the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during April 2013, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI

Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

Table 1--Original and Supplemental NADAs and ANADAs Approved During April 2013

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
200-538	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	CLINDAMED (clindamycin hydrochloride) Oral Drops	Original approval as a generic copy of NADA 135-940	520.447	yes	CE ¹
200-551	Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101	Enrofloxacin Flavored Tablets	Original approval as a generic copy of NADA 140-441	520.812	yes	CE ¹

¹The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment (EA) or an environmental impact statement (EIS) because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.447 [Amended]

2. In paragraph (b) of § 520.447, remove “and” and add “, and 061623” after “058829”.

3. Revise § 520.812 to read as follows:

§ 520.812 Enrofloxacin.

(a) Specifications. Each tablet contains 22.7, 68.0, or 136.0 milligrams (mg) of enrofloxacin.

(b) Sponsors. See Nos. 000859 and 026637 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs and cats--(1) Amount. Administer orally as a single, daily dose or divided into two equal doses at 12-hour intervals.

(i) Dogs. 5 to 20 mg per kilogram (/kg) (2.27 to 9.07 mg per pound (/lb)) of body weight.

(ii) Cats. 5 mg/kg (2.27 mg/lb) of body weight.

(2) Indications for use. For the management of diseases associated with bacteria susceptible to enrofloxacin.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

Dated: May 16, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2013-12134 Filed 05/21/2013 at 8:45 am; Publication Date: 05/22/2013]